

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
NEW ENGLAND)
HOME THERAPIES)
DS3486)

PHA-2014-0034

CEASE AND DESIST AND QUARANTINE NOTICE

1. New England Home Therapies Inc., Registration No. DS3486, 337 Turnpike Road, Southborough, Massachusetts, is hereby notified to **IMMEDIATELY CEASE AND DESIST** the compounding of sterile medications and the dispensing of compounded sterile medications.
2. This Notice is issued pursuant to the authority of the Department of Public Health ("Department") through the Board of Registration in Pharmacy ("Board") and the Division of Food and Drugs, pursuant to M.G.L. c. 94, § 189A, M.G.L. c. 94C, §§ 13 and 14, M.G.L. c. 112, §§ 39 and 42A, and Board Regulation 247 CMR 10.08, related to observed pharmacy practices and conditions at New England Home Therapies facility.
3. New England Home Therapies was observed to be non-complaint with the requirements of Board regulations, 247 CMR 2.00 *et seq*, and United States Pharmacopoeia ("USP") Chapter <797>, Pharmaceutical Compounding – Sterile Preparations. Deficiencies include, but are not limited to, Board regulations and USP <797> standards pertaining to environmental monitoring and primary and secondary engineering controls and the failure to report abnormal environmental monitoring results as required by 247 CMR 6.15(7).
4. New England Home Therapies must immediately cease the preparation and dispensing of compounded sterile medications (Schedules II through VI). Pursuant to this Notice, no dispensing of sterile compounded medications may occur without the express approval of the Department.

5. New England Home Therapies must immediately QUARANTINE all (1) compounded sterile medications (Schedules II through VI) located on New England Home Therapies premises; and (2) sterile medications and pharmaceuticals contained in opened manufacturer stock bottles or other type of manufacturer packaging on New England Home Therapies premises. No disposition may be made of ANY of the above-referenced controlled substances subject to this QUARANTINE NOTICE without the express approval of the Department. Removal or disposition of the above-described articles without permission from the Department shall be subject to applicable statutory and regulatory penalties.
6. New England Home Therapies may not resume the compounding or dispensing of compounded sterile medications without the express approval of the Department. New England Home Therapies shall conduct an orderly transition of patient care and pharmacy related compounding services.
7. In accordance with 247 CMR 10.08, a hearing limited to the determination of the necessity of this Notice shall be afforded to the licensee within 15 business days of the issuance of this Notice.
8. Direct questions to David Sencabaugh, Executive Director, Board of Registration in Pharmacy, 617-973-0993.

BOARD OF REGISTRATION IN PHARMACY

Patrick Gannon (HAE)

Patrick Gannon, R.Ph

President-Elect

Effective Date: February 26, 2014

Acknowledgement of receipt by
New England Home Therapies

Date: _____

Time: _____

Print Name: _____